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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,293	08/20/2003	John R. Peery	000952-103	7202
24247	7590	05/17/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EBRAHIM, NABILA G	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,293	<b>Applicant(s)</b> PEERY ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/7/06</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on \*\*\* has been entered.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 51, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Laby et al. US 4623330 (hereinafter "Laby").

Laby teaches an implantable device (example 4), for delivering a pharmaceutical and veterinary applications (col. 1, lines 5-10). A hollow tubular body adapted to contain a solid, paste or liquid material, one end of said body being at least partly open to allow egress of the material, the other end of said body being closed, a gas tight plunger adapted for slidable movement within the body (col. 1, lines 57-63). The hollow body portion comprises a cylindrical tube open at one end, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening (col. 1, lines 43-47).

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laby et al. US 4623330 in view of Magruder et al. US 5238687 (hereinafter "Magruder") and further in view of Mia US 5519002 (hereinafter "Mia").

The helical spring is made from spring steel wire having a circular cross-section of 0.5 mm in diameter (0.0197 inch), which is within the range set forth in claim 52. Laby also discloses a radially expanding disc to ensuring good tight contact between the piston and the walls of the body (col. 2, lines 62-67). The tubular body has a gas-

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permeable membrane, which is obvious on the semipermeable membrane recited in the instant claims.

Laby fails to disclose the semipermeable membrane recited in the instant claims.

Magruder discloses a delivery implantable device that includes a sleeve to protect the delivery device from transient mechanical forces. The invention provides a fluid-imbibing delivery device comprising a housing enclosing an internal compartment having a first wall section that substantially restricts the passage of fluid into the delivery device, i.e. is substantially fluid-impermeable (abstract). The implantable device contains at least one expandable driving member (abstract). The composition of the circumferential sleeve may be of a semipermeable material made of polyamide or polyurethane (col. 9, lines 22, and 23), or in a preferred embodiment, they are selected from the group consisting of a cellulose ester, a cellulose ether and a cellulose ester-ether, which are cellulosic polymers (col. 9, lines 62-64). The invention comprises a lubricated elastomeric piston inserted on top of the osmotic device to be flush with the top of the semipermeable walled member (col. 15, lines 5-8).

Neither of the references discloses LHRH agonists.

Mia teaches a method for preventing conception in mammals, the drug used is LHRH agonists (abstract and claim 1) and the administration method can be an implant (claim 8). The effect of the drug conjugate starts from about 6 weeks after administration until the LHRH antibodies formed in response to the conjugate are metabolized, generally about 0.5-2 years (abstract), in a preferred embodiment a

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composition comprising free LHRH or an analog thereof and an immunogenic conjugate between a protein mixtures thereof is administered to mammals to prevent conception over the period from initial injection to about 2-3 years (col. 3, lines 33-44).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the implantable device of Laby and provide it with the sleeve made of cellulosic material or polyurethane and administer LHRH agonist through it because Mia states that the invention is effective in mammals soon after administration of the composition and stay effective for extended period. The expected result would be an implantable device that delivers LHRH for an extended period of time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

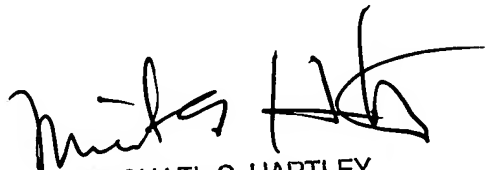
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

4/10/06



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER